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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,874	11/14/2002	Jasmid Tanha	11054-1	8696
25277	7590	02/02/2005	EXAMINER	
BLANCHARD, DAVID J				
		ART UNIT	PAPER NUMBER	
		1642		
DATE MAILED: 02/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,874	TANHA ET AL.	
	<b>Examiner</b> David J Blanchard	<b>Art Unit</b> 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b])**

- a)  The period for reply expires \_\_\_\_ months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.  The proposed amendment(s) will not be entered because:

- (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  they raise the issue of new matter (see Note below);
- (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-3, 5-9 and 25-30.

Claim(s) withdrawn from consideration: 10-24 and 31-40.

8.  The drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s) ( PTO-1449 ) Paper No(s). \_\_\_\_\_.

10.  Other: \_\_\_\_\_.

LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

Continuation of 2. NOTE: If, if, if entered, applicant's amendments to the claims introduce NEW MATTER into the disclosure. The amendments to the claims recite a phage display library of non-immunized llama antigen-binding fragments in phage vectors wherein at least  $10^9$  different fragments are represented in the library. At page 12 of the specification, it is disclosed that the use of a phage vector for the library construction is preferred, it also discloses that fd-tet based libraries are often of small size (i.e.,  $10^5$ - $10^6$ ) and library propagation in the absence of tetracycline resulted in a llama VHH library of size of approximately  $8.8 \times 10^8$ , which is the largest size library ever obtained using the fd-tet vector. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the amended claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Further, the statement at page 12 of applicant's specification "This is the largest size library ever obtained using fd-tet vector." raises new issues under 35 U.S.C. 112, first paragraph, enablement with respect to the scope of the claims as amended. The amendments to the claims change the scope and raise new issues, which require further consideration and search.



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER